

## **DETAILED ACTION**

### ***Response to Applicant's Amendment and Arguments***

1. The amendment filed February 3, 2010, has been entered and made of record.
2. Applicant's arguments have been fully considered, but are not deemed to be persuasive for at least the following reasons.
3. On page 12 of the response, Applicant alleges that Packer does not display a real-time or current image, but rather displays the previously generated MRI image interpolated to approximate the current cardiac phase of the patient. Applicant further argues that Packer does not display any part of the real-time image, but instead uses the ultrasound data to determine the current location of the medical device, and overlays a representation of it on the interpolated previously generated MRI image.
4. The Examiner disagrees. Packer discloses a current real time image from transducer 30, at column 9, lines, 21-22. Note that this image is processed to put into a form which can be used with the registration process, column 9, lines 27-29. The image from transducer 30 includes the medical device 56, column 8, lines 54-56. As explained by Packer, this permits a physician to monitor use of the device. As noted also at column 10, lines 23-25, the real-time images include the medical device. See also column 2, lines 53-60. The image of the medical device is then overlaid on the high resolution anatomical image, column 10, lines 30-34. Note that while an icon that represents the device or a cursor or cross-hairs can be overlaid, Packer explicitly teaches that the actual image of the medical device is overlaid. Packer further states that the invention provides the physician with a continuously updated image of the

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subject anatomy and the medical device (column 10, lines 37-40) and allows the physician to more accurately manipulate the ablation device (column 10, lines 45-47). It is also noted that the while interpolated images can be used for the high resolution anatomical images (column 9, lines 48-52), they can also be stored 3D high resolution images at successive positions during the heart cycle (column 9, lines 42-44). Clearly, Packer does disclose displaying a real-time image. It is noted that Packer does disclose an embodiment in which a medical device may not be displayed (e.g., the electrode array, column 2, lines 42-44). However, this is not the embodiment being relied upon in rejecting the claims.

5. On the paragraph bridging pages 12 and 13, Applicant argues that Packer does not describe reconstructing an ultrasound image and combining it with an MRI image, but instead uses the ultrasound data as distance gauging signals to determine the location of the ultrasound device. Applicant alleges that Packer's system does not generate an image of the medical device which is carrying the ultrasound probe. The Examiner disagrees. As stated previously, the medical device 56 is within the field of view of the transducer 30 (column 8, lines 54-56), and the ultrasound transducer 30 produces real-time images (column 9, lines 21-22). The image of the medical device is overlaid on the anatomical image (column 10, lines 30-34).

6. Regarding claim 13, Applicant argues (paragraph bridging pages 13 and 14), that Packer interpolates the MRI map image to a current cardiac phase of the patient and superimposes an icon or other representation of the medical device on the map image. The Examiner points out that Packer's invention can interpolate if there are not enough

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high resolution images (i.e., a high resolution image is available at the moment indicated by the phase counter, column 9, lines 48-52), but this is not necessary if there are sufficient high resolution images. Further, as previously explained, Packer does disclose overlaying the image of the medical device. Therefore, Packer does disclose combining the map image around the estimated position of the object with the current image.

7. Regarding claim 20, Applicant again argues that Packer's ultrasound data does not include a representation of the medical device, and the medical device is thus not depicted in a current ultrasound image. The Examiner again disagrees, and refers to the explanation above regarding this topic.

### ***Claim Objections***

8. Claim 1 is objected to because of the following informalities: in line 16 of claim 1, "close" should read "closely". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 20-22, 24-25, 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. Claim 20 now recites, “motion states”. The claim requires, “...map images corresponding to each of a plurality of the motion states.” These features are not supported in the original specification. Previously, the claim (as well as other claims) referred to the “dwell region”. The use of the term “dwell” would imply the lack of motion, and would thus seem to oppose the term “motion”. Furthermore, the disclosure as originally filed does not even include the term “motion”.

12. In claim 20, the “processor programmed for...” is not supported by the original disclosure. The original disclosure does not disclose a programmed processor. See also claims 24-25 and 35-36.

13. Claim 33 recites a “tangible computer-readable medium...” This is not supported by the original disclosure. While Applicant’s specification does disclose a memory at various locations, the memory is only described as storing map images. There is no disclosure of a memory or tangible computer-readable medium carrying instructions for controlling a processor.

### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 13 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,556,695 to Packer et al. (hereinafter referred to as "Packer"), in combination with U.S. Patent 7,280,710 to Castro-Pareja et al. (hereinafter referred to as "Castro-Pareja).

16. Regarding Claim 13, Packer discloses a method for combining a current image of an object (Col.8, Lines 47-50 and Col.9 21-24) and a map image of the dwell region of the object (Col.9, Lines 37-52), comprising a memory for storing a number of map images which are categorized according to a varying state of the dwell region of the object (column 9, lines 42-52), the method comprising with a processor, performing the following steps:

- a) estimating the position of the object in the current image in relation to the map image (as indicated at column 2, lines 53-60, column 10, lines 30-32; the location of the device is estimated, and it is in relation to the map image since the real time images are being overlaid on the anatomical image), and

- b) combining the map image around the estimated position of the object with the current image, the estimated position of the object in the map image being brought into register with the actual position of the object in the current image using at least a section of the map image which covers the region around the object (Col.10, Lines 31-36).

17. Packer does not disclose wherein the current image and the map image are from different imaging sources. However, this is well known in the art. For example, in an

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analogous environment (column 5, lines 53-63) Castro-Pareja discloses registering images of different modalities (column 5, lines 53-54; column 27, lines 15-21). Packer discloses that the system works with a variety of imaging sources (column 3, lines 59, 67). Further, Castro-Pareja's invention permits fast registration (column 1, lines 12-14) and the use of different sources allows accurate localization of structures. Therefore, it would have been obvious to one of ordinary skill in the art to modify Packer's system according to Castro-Pareja.

18. As to claim 33, Packer discloses a tangible computer-readable medium carrying instruction for controlling a processor to perform the method of claim 13 (column 4, line 12).

19. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Packer, in combination with Castro-Pareja, and in further combination with any one of the following two references: U.S. Patent 5,285,786 to Fujii (hereinafter referred to as "Fujii"), or U.S. Patent 6,859,548 to Yoshioka et al. (hereinafter referred to as "Yoshioka").

20. Regarding claim 19, Packer discloses the method of claim 13, but does not disclose wherein in the step of combining at least the section of the map image with the current image, only the section of map image which just covers the region around the object is combined with just a section of the current image which just covers the region around the object; and generating a display of the current image with just the region

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around the object being a combination of corresponding sections of the map image and the current image. However, this is well known in the art.

21. For example, this limitation reads on at least two portions of Fujii. First, Fujii teaches combining images via subtraction, wherein mask image and contrast image data are subtracted (column 7, lines 38-44). As can be seen in Fig.4, if one considers the object to be the contents of image 110, and the map image to be image 100, then the section of the map image 100 just covers the region around the object. Second, Fujii also teaches (column 7, line 63 to column 8, line 15) superimposing two images by using a preset value of brightness where the x-ray image data from a first coexists with blood vessel image data from a second image, effectively using only that section of the map image (i.e., the blood vessel image data) which just covers the region around the object (i.e., from element 125 in Fig.4). Fujii states that its invention can provide a good grasp of the relative position of a catheter inserted into a blood vessel (column 2, lines 27-40). Therefore, it would have been obvious to one of ordinary skill in the art to modify Packer according to Fujii. In the combination, the resulting generated display would comprise just the region around the object.

22. As an alternative example, Yoshioka teaches superimposing the picture of a contour region over an original picture (column 18, lines 38-45). This is done by replacing only the pixel values in the portion of the original picture which correspond to the region within the contour region (column 17, lines 46-53). Therefore, only a section of the map image (e.g., original picture) which just covers the region around the object (e.g., the contour region) is used. Yoshioka's invention provides the advantage of

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lessening the burden to the inspector and obtaining objective, accurate inspection result, and can allow local movement states of the cardiac wall to be easily evaluated (column 2, lines 53-63). Therefore it would have been obvious to one of ordinary skill in the art to modify Packer according to Yoshioka. In the combination, the resulting generated display would comprise just the region around the object.

### ***Allowable Subject Matter***

23. Claims 1, 8-9, 27-30 are allowed.

24. Claims 31-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JON CHANG whose telephone number is (571)272-7417. The examiner can normally be reached on M-F 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached on (571)272-7453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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